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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--|-------------|----------------------|---------------------|------------------|
| 10/072,327 | 02/06/2002 | Franck Bellon | EGYP-020 | 3147 |
| 530 | 7590 | 01/11/2005 | EXAMINER | |
| LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090 | | | GORDON, BRIAN R | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1743 | |

DATE MAILED: 01/11/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------------------|---------------------------------------|--|
| Office Action Summary | Application No. 10/072,327 | Applicant(s) BELLON, FRANCK | |
| | Examiner Brian R. Gordon | Art Unit 1743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2-6-02.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 and 24-42 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 2-6-02 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>8-30-02; 1-23-03</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Drawings

1. The drawings are objected to because the application contains a drawing labeled "Figure to be Published" after page 5, which is not required in the US Application. The drawing appears to be a duplicate of Figure 2. The sheet should be removed from the application.

Specification

2. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to **a single paragraph** on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

Applicant's abstract contains the legal phrase "comprising". The last line in reference to figure 2 should be deleted.

The following guidelines illustrate the preferred layout for the specification of a utility application. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

As provided in 37 CFR 1.77(b), the specification of a utility application should include the following sections in order. Each of the lettered items should appear in upper case, without underlining or bold type, as a section heading. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) TITLE OF THE INVENTION.

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- (b) CROSS-REFERENCE TO RELATED APPLICATIONS.
- (c) STATEMENT REGARDING FEDERALLY SPONSORED RESEARCH OR DEVELOPMENT.
- (d) INCORPORATION-BY-REFERENCE OF MATERIAL SUBMITTED ON A COMPACT DISC (See 37 CFR 1.52(e)(5) and MPEP 608.05. Computer program listings (37 CFR 1.96(c)), "Sequence Listings" (37 CFR 1.821(c)), and tables having more than 50 pages of text are permitted to be submitted on compact discs.) or REFERENCE TO A "MICROFICHE APPENDIX" (See MPEP § 608.05(a). "Microfiche Appendices" were accepted by the Office until March 1, 2001.)
- (e) BACKGROUND OF THE INVENTION.
 - (1) Field of the Invention.
 - (2) Description of Related Art including information disclosed under 37 CFR 1.97 and 1.98.
- (f) BRIEF SUMMARY OF THE INVENTION.
- (g) BRIEF DESCRIPTION OF THE SEVERAL VIEWS OF THE DRAWING(S).
- (h) DETAILED DESCRIPTION OF THE INVENTION.
- (i) CLAIM OR CLAIMS (commencing on a separate sheet).
- (j) ABSTRACT OF THE DISCLOSURE (commencing on a separate sheet).
- (k) SEQUENCE LISTING (See MPEP § 2424 and 37 CFR 1.821-1.825. A "Sequence Listing" is required on paper if the application discloses a nucleotide or amino acid sequence as defined in 37 CFR 1.821(a) and if the required "Sequence Listing" is not submitted as an electronic document on compact disc).

The proper section headings are missing from applicant's disclosure which makes it difficult to determine where one section ends and the next begins.

3. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.
4. Claim 2 is objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. Claim 2 depends upon

claim 1; however the claim only recites the same structural limitations of claim 1 and fails to add any additional structural limitations of those previously claimed.

5. Claim 23 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim must should refer to other claims in the alternative form only. See MPEP § 608.01(n). Accordingly, the claim 23 has not been further treated on the merits.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 3, 4, 11-14 17-18, 24, 33, 42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 3 recites the projecting element is in the shape of a parallelepiped figure and it also constitutes a slope. It is unclear how the projection could be described as both. It is understood that a parallelepiped is a 3-dimensional object or 6-faced polyhedron (such as a cube) all of which faces are a parallelograms. Parallelograms do not form a slope. Therefore, the projection cannot be both. If the projection creates a slope, it is more of a trapezoid shape as seen in applicant's figure 6.

Claim 4 recites the projecting element comprises mutually parallel upper and lower surfaces and further more creates a slope. It is unclear what the term "mutually" is intended to portray. Is the term to establish that the surfaces are nearly or almost parallel? If so, the term is considered relative. Applicant does not give a definition or

numerical value in the claim for one to determine what degree of deviation from parallel is considered "mutually parallel". As such for the purpose of examination the examiner assumes the upper and lower surfaces are parallel. Therefore, there would be no slope of the bottom surface.

The term "mutually parallel" in claims 4 and 11-14 is a relative term which renders the claim indefinite. The term "mutually parallel" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. What one considers mutually parallel varies from one's own perspective.

Claims 17 and 18 do not further structurally limit the device, but yet expressed particular way in which applicant intends for the device to be used to perform the depositing of each reagent.

It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate the claimed apparatus from a prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

The functional recitation "for depositing each reagent....to the analytical support" has not been given patentable weight because it is in narrative form. In order to be given patentable weight, a functional recitation must be expressed as a "means" for performing the specified function, as set forth in 35 USC 112, 6th paragraph, and must be supported by recitation in the claim of sufficient structure to warrant the presence of the functional language. *In re Fuller*, 1929 C.D. 172; 388 O.F.279.

Claim 24 recites the limitation "the fixative" in line1. There is insufficient antecedent basis for this limitation in the claim.

In claim 33 "a mask" is recited in the loading step and "a mask (10) according to claim 1" is recited in the positioning step. This makes the claim appear as if applicant is

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referring to two different masks. It is suggested applicant amend the loading step to recite "a mask according to claim 1" and the positioning step to recite "the mask".

Claim 42 appears to be a process limitation. If applicant intends to claim the reagent, the examiner suggests the language of: "The mask according to claim 1, further comprising freeze dried reagents loaded into the opening."

Dependent claims 2-3, 5-27 and 42, should be amended to recite "The mask" rather than "A mask".

Dependent claims 30 and 31, should be amended to recite "The device" rather than "A device".

Dependent claims 34-38, should be amended to recite "The method" rather than "A method".

Dependent claim 41, should be amended to recite "The kit" rather than "A kit".

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-8, 10-12, 15-18, 21, 27, and 40 are rejected under 35 U.S.C. 102(e) as being anticipated by Ramstad 6,632,660.

Ramstad discloses an assembly for transferring a liquid to a substrate (analytical support) such as a well plate. The assembly comprises a platen including an array of apertures extending therethrough, and with each of the apertures being disposed at a position corresponding to a respective one of the wells of the array.

With reference to FIG. 6, the platen 16 (with upper and lower surface) includes passages or **through-holes 34** (opening with upper and lower orifices) that are concentric, and directly correspond to, the wells of the microplate 18. Except for such through-holes, the platen is configured to substantially cover the supports. The platen 16 further includes ring-like **projections 36** (protuberance) (FIG. 6B) extending from a major surface (lower surface) thereof, denoted as 16a, with each ring-like projection circumscribing, and further defining, a respective one of the through-holes 34. Such construction permits access to the individual wells of the microplate from a region extending above each of the wells. As can be seen in FIGS. 1A and 1B, the outer circumferential region of each ring-like projection 36 is configured with a taper (creates a slope relative to surface) along a direction extending away from the major surface 16a of the platen 16.

The projections are aligned in an array or rows constituting lanes as claimed by applicant.

The die plate 14, platen 16, and microplate 18 can be formed by any conventional means, with injection molding being one suitable technique. According to various embodiments, these components can be constructed of **any substantially rigid**, water-insoluble, fluid-impervious material that is substantially chemically non-

reactive with the biochemicals, samples, reagents, etc. intended for use therewith. The term "substantially rigid" as used herein is intended to mean that the material will resist deformation or warping under a light mechanical or thermal load, although the material may be somewhat elastic. Suitable materials include acrylics, polycarbonates, polypropylenes and polysulfones (column 6, lines 30-65).

The device further comprises supports (positioning means) for the assembly. Each of the sheet-like supports 12a-h can include one or more location features to facilitate alignment with respect to the other system components. For example, as shown in FIGS. 2 and 3, slots 22 can be formed at selected locations along the edge regions of each of the supports 12a-h. The slots 22 can be positioned and configured to mate with complementary-shaped regions of one or more of the microplate 18, die plate 14, and/or platen 16. (column 5, lines 28-35)

In the event applicant amends claims 3 and 4 to classify the protuberance as constituting a slope (only and not having parallel faces/surfaces), the claims would be rejected as above.

10. Claims 1-12, 15-18, 21, 27, and 40 are rejected under 35 U.S.C. 102(b) as being anticipated by Hanaway et al. US 5,000,921.

Hanaway et al. disclose a pipette sampling device (mask) for removing and transferring a plurality of liquid samples consists of an improved structure which allows a low cost manufacturing process, the use of a minimum amount of material in such process, and a pipette cavity shaped such that hydraulic principles insure accuracy during filling and dispensing to substrates such as microwell plates (analytical support).

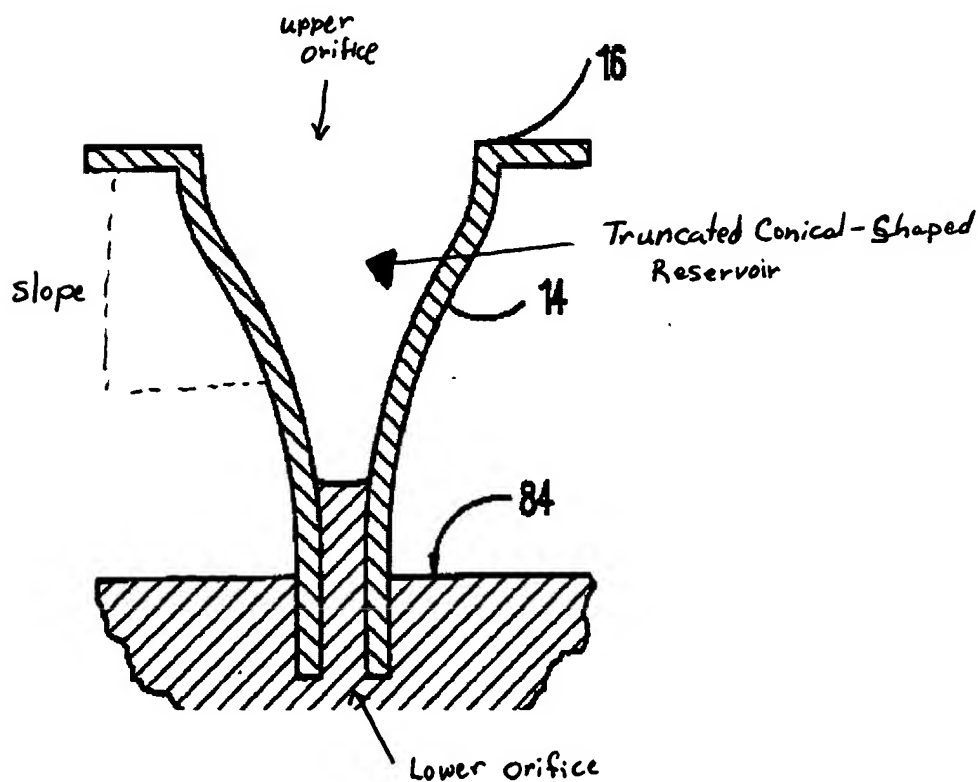
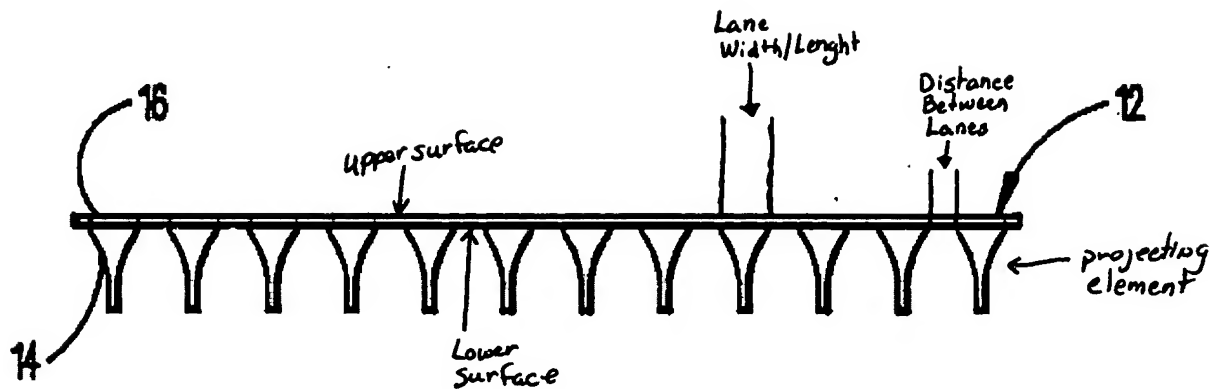
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The pipette sampling device is positionable within a filling tray which permits an initial filling of the pipettes by a liquid through **capillary action**.

The pipette sheet 12, as illustrated in FIGS. 1 and 2, is an array of 96 pipette cavities 14 depending downwardly from an integral flat sheet 16. A precision die is used to thermoform a 0.015 to 0.020 inch polyvinylchloride (PVC) plastic (rigid material) sheet so that each cavity 14 is identical.

Refer to labeled figures below for examiners interpretation of elements equivalent to as claimed by applicant.

In the event applicant amends claims 3 and 4 to classify the protuberance as constituting a slope (only and not having parallel faces/surfaces), the claims would be rejected as above.



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11. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

12. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

13. Claims 19-20, and 22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ramstad or Hanaway et al. as applied to claims 1 and 4 above, and further in view of Marquiss et al. US 6,838,051.

While both Ramstad and Hanaway et al. disclose using a transferring device comprising an array of cavities equivalent to that of a standard 96 well microplate, neither reference discloses the specific spacing between each individual cavity in the array nor the diameter (lane spacing) of each cavity.

While it's conventionally known in the art, Banker et al discloses 96, 384, 864, 1536, and 3456 well microplates formats with the center-to-center spacing of 9 mm (in 96 well) in both directions, since the well-to-well spacing in all the above-mentioned plates is 9 mm or an integer fraction thereof (e.g., 4.5 mm, 2.25 mm, etc.). It is further

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know that the diameter of each well in a 96 well format be 4.5 mm and any interger fraction thereof respectively.

It would have been obvious to one of ordinary skill in the art at the time of the invention to recognize that the spacing between the lanes of each transferring device as taught by Ramstad and Hanaway et al. would have a lane-spacing and lane-separation of 1.5 mm or more and a lane with of 2.5.

Double Patenting

14. Claims 1-22 and 24-42 of this application conflict with claims 1-41 of Application No. 10/359,323. 37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

15. A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

16. Claims 1-7, 9-22, 24-28, 30-33, 37, 39, 40 and 42 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1-7, 8-21, 23-27,

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29-32, 36, 38, 39, and 41 of copending Application No. 10/359,323. This is a provisional double patenting rejection since the conflicting claims have not in fact been patented.

17. Claims 8, 29, 34-36, 38, and 41 provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 7, 28, 33-35, 37, and 40 of copending Application No. 10/359,323. Although the conflicting claims are not identical, they are not patentably distinct from each other because the only difference in the respective claims is the dependency. The claims in the copending application 10/359,323 are either dependent upon a similar independent claim or erroneously dependent upon themselves.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion


18. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Yiu, Felix H.; Roberts, Roger Q. et al.; Ingenhoven, Nikolaus et al.; Tseng, Fan-Gang et al.; Roberts; Roger Q. et al.; Yao; Xian-Wei; Aoki; Dennis; Baier; Joerg; Gavet; Louis et al.; and Fawcett; Kevin R. et al. disclose liquid transferring devices.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian R. Gordon whose telephone number is 571-272-1258. The examiner can normally be reached on M-F, with 2nd and 4th F off.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


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